

5/16/05

By Bernadine Healy, M.D.

Mean-Street Medicine

One of the nasty little secrets surrounding prescription drugs is that they don't always find their way from drug company to needy patients without some dangerous detours. Because of a numbingly complex network of middlemen, it's easy for crooks to sneak in and adulterate, spoil, and intentionally mislabel enough good medicine to make millions on the side. It's estimated that counterfeits represent less than 1 percent of our drug supply, but they are on the rise, particularly among the newer, more expensive brands.

How can this happen in America? Aren't we the ones who righteously outlaw a prescription filled in a Canadian drugstore for fear of fakery? Investigative reporter Katherine Eban in her new book, *Dangerous Doses*, out this week, will tell you that Canada is not the problem. It's our own poorly regulated distribution system. Eban provides a riveting account of a 2 1/2-year investigation in south Florida in which corrupt middlemen, many with criminal records, worked a typical scam: Drugs, sometimes stolen, were hidden in old paint cans or unmarked boxes and moved around in their hot SUVs. Shady "repackagers" diluted or "up-labeled" vials and containers as higher-dose, higher-priced products. The adulterated drugs were then released back into the legitimate drug-supply chain.

Bartering in the shadows like peddlers of fake designer watches, these drug thugs have it easy. Since drugs are consumed, evidence is gone without the victims or their doctors having a clue as to why their medicine failed them. Drug counterfeiting draws soft penalties, and it's hard to prosecute since the wholesalers leave no audit trails. Like expensive pets, drugs are supposed to carry papers of their "pedigree," listing all transactions. But phony papers and loopholes make compliance a joke. There are also lawful opportunities to wipe pedigrees clean when drugs are resold, in effect making them virgin products, despite having passed through numerous hands.

About 90 percent of drugs in this country are handled by the Big Three companies: AmerisourceBergen, Cardinal Health, and McKesson, the primary distributors who offer efficient one-stop shopping for pharmacies, medical institutions, and mass merchandisers. But more than 6,000 small wholesalers work the secondary market by buying up odd lots or excess products from whomever they can, including the Big Three, drugstores, and nursing homes or clinics overstocked with deeply discounted drugs. They resell to other wholesalers, pharmacies, or back to the big distributors at prices often lower than manufacturers charge. With all this back and forth, it's no wonder spoiled or counterfeit drugs can seep in. Even a small amount of mean medicine mixed with the good contaminates the whole system. Though manufacturers and big distributors have voluntarily tightened up dealings with small wholesalers, the problem still festers.

Racketeers. As Eban recounts, the Florida scam was blown wide open by a "ragtag" group of seasoned investigators who seem as if they were cast right out of an episode of *The Wire*. Calling themselves "Horsemen of the Apocalypse," they teamed with determined

state prosecutors, including one who herself is on insulin for diabetes. They pursued the perpetrators with the passion usually directed at mob racketeers or murderers, and their storied success led to tough counterfeit laws in Florida. But this is about more than Florida.

Though manufacturers have a system to gather and share among themselves information on counterfeit drugs in all states, their findings are kept out of public view for fear that they might lead people to stop taking needed medicines. But the 2005 Global Pharmaceutical Report, called Progressions and released last week by Ernst & Young, states that nearly three quarters of manufacturers see the secondary wholesale market as a threat to both their good names and unwitting victims. Meanwhile, the Food and Drug Administration has been restrained in its ability to audit wholesale or retail transactions and in demanding new electronic "track and trace" technology.

As we smoke out offshore Internet pharmacy crooks and endlessly debate buying drugs from Canada, let's put our own house in order. Drug thugs enriching themselves with crimes that harm the sick will surely find their own dark place in hell. Until then, some heavy-duty perp walks in broad daylight are in order.

Copyright © 2005 U.S.News & World Report, L.P. All rights reserved.
Use of this Web site constitutes acceptance of our Terms and Conditions of Use and Privacy Policy.